K102291

510(k) Summary of Safety and Effectiveness

SUBMITTER: Surgical Devices, a global business unit
of Tyco Healthcare Group LP (d/b/a Covidien)
60 Middletown Avenue
North Haven, CT 06473
Tel. No.: (203) 492-5352

SEP 15 2010

CONTACT PERSON: Tim M. Lohnes, Manager, Regulatory Affairs

DATE PREPARED: August 10, 2010

TRADE/PROPRIETARY NAME: Covidien Endo GIA™ Radial Reload with Tri-Staple™ Technology

COMMON/USUAL NAME: Surgical Stapler with Implantable Staple

CLASSIFICATION NAME: Staple, Implantable

PREDICATE DEVICE(S): Autosuture™ ENDO GIA™ Stapler (K083519),
Ethicon Contour Curved Cutter Stapler & Reloads (K091322)

DEVICE DESCRIPTION:

The Endo GIA™ Radial Reload with Tri-Staple™ Technology is a curved stapler cartridge that places three staggered rows of staples on either side of a cut line and simultaneouly divides (cuts) the tissue between the rows.

Covidien Reloads with Tri-Staple™ Technology apply height progressive rows of titanium staples on either side of the cut line. The shortest staple length is located in the first staggered row nearest the knife, an intermediate staple length is located in the second row, and the longest staple length is located in the third (outside) staggered row.

The Endo GIA™ Radial Reload with Tri-Staple™ Technology is compatible with the Endo GIA™ ULTRA Universal Stapler and GIA™ and Endo GIA™ Universal Stapler handles, and incorporates the functionality of those handles including interlocks to prevent firing a previously fired cartridge.

INTENDED USE:

The Endo GIA™ Radial Reload with Tri-Staple™ Technology has application in open or minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, i.e. low anterior resection.

It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

TECHNOLOGICAL CHARACTERISTICS:

This 510(k) reports a modification of our currently marketed Autosuture™ Endo GIA™ Staplers (K085319), namely, the Endo GIA™ Radial Reload with Tri-Staple™ Technology applies staple radial, rather than linear staple lines from a curved, rather than straight, cartridge. The subject Endo GIA™ Radial Reload with Tri-Staple™ Technology incorporates identical Tri-Staple™ Technology and uses the existing Endo GIA™ Stapler handles for operation. It will be offered in a 60 mm length as a Purple "Medium-Thick" cartridge.

The Endo GIA™ Radial Reload Purple with Tri-Staple™ Technology is identical to the predicate Autosuture™ device with regard to stapling technologies. The curved cartridge facilitates access in restricted anatomy, for example low in the pelvis during lower anterior resection (LAR) with total mesorectal excision (TME) procedures. The Endo GIA™ Radial Reloads Purple with Tri-Staple™ Technology are compatible with the existing Endo GIA™ Stapler handles for operation and incorporate the functionality of those handles, including interlocks to prevent firing a previously fired cartridge.

The subject device is equivalent to the predicate Ethicon Contour® Curved Cutter Stapler, which applies radial staple rows on either side of a cut line and divides between them, creating a 40mm curved transection. The Endo GIA™ Radial Reload Purple with Tri-Staple™ Technology places three radial staple rows 60mm in length and simultaneouly divides (cuts) between the rows, creating a 60mm curved transection.

MATERIALS:
All components of the Endo GIA™ Radial Reloads with Tri-Staple™ Technology are comprised of materials that are in accordance with ISO Standard 10993-1.

PERFORMANCE DATA:
Bench and animal model performance evaluations were completed to verify that the EndoGIA™ Radial Reload Purple with Tri-Staple™ Technology is safe and effective and performs as intended. Testing consisted of evaluation for in vitro staple formation, firing force and staple line pull-apart force, as well as in vivo staple formation, free bleed, burst strength, air leak, tissue grasping, and trauma.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Covidien
% Mr. Tim M. Lohnes
Manager, Regulatory Affairs
60 Middleton Avenue
North Haven, Connecticut 06473

SEP 15 2010

Re: K102291
Trade/Device Name: Covidien Endo GIA™ Radial Reload with Tri-Staple™
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: August 10, 2010
Received: August 12, 2010

Dear Mr. Lohnes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Peter Rumm MD
Dep Dir

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K102291

510(k) Number (if known): K102291

SEP 15 2010

Device Name:

Indications For Use

510(k) Number (if known):
Device Name: Covidien Endo GIA™ Radial Reload with Tri-Staple™ Technology

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It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Kraus for MKC

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102291